UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JULIAN QUINONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. FREQUENCY THERAPEUTICS, INC., DAVID L. LUCCHINO, and CARL LEBEL, Defendants.	Case No. 1:21-cv-10933-WGY **CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Lead Plaintiff Julian Quinones ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, alleges the following based upon personal knowledge, as to Plaintiff and Plaintiff's own acts, and upon information and belief, as to all other matters, based on the investigation conducted by and through Plaintiff's attorneys, which includes, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings made by Frequency Therapeutics, Inc. ("Frequency" or the "Company"), the Company's Chief Executive Officer ("CEO") David L. Lucchino ("Lucchino"), and the Company's Chief Development Officer ("CDO") Carl LeBel ("LeBel"), analyst and media reports, Company press releases, interviews with former Company employees, message boards specifically discussing the Company, and other publicly available information. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein.

SUMMARY OF THE ACTION

1. This is a federal securities action on behalf of a class consisting of all persons who purchased or otherwise acquired Frequency's common stock between October 29, 2020, and March 22, 2021, inclusive (the "Class Period") seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). This action brings claims against Defendants Frequency, CEO Lucchino, and CDO LeBel, and seeks to recover damages caused by Defendants' violations of the Exchange Act.

2. Frequency is a publicly-traded pharmaceutical company. During the relevant period, the Company was headquartered in Woburn, Massachusetts and incorporated in Delaware but recently relocated its headquarters to Lexington, Massachusetts. Frequency is focused on the development and commercialization of a hearing loss treatment titled "FX-322," which the Company has long promoted as a potential treatment for patients with severe sensorineural hearing loss ("SNHL").

3. Frequency has conducted multiple clinical trials assessing the safety and efficacy of FX-322. The Company announced promising safety and efficacy results from Phase 1 and Phase 1/2 trials, which previously indicated that FX-322 was likely safe and may have a beneficial effect on patients that suffered from SNHL. However, the Company's Phase 1 initial studies intentionally only enrolled a handful of patients — up to 22 in the Phase 1/2 study — and these studies did not have a sufficient number of patients to fully evaluate the effects of FX-322 on the treatment of SNHL (but could determine that the drug was likely safe for use in humans).

4. In light of the preliminary "successes" in the Phase 1 trials, in October 2019, the Company launched a Phase 2a trial of FX-322 ("Phase 2a"). As described in an October 2020 investor presentation starting the Class Period, the "objectives" of Phase 2a were to: (i) "further establish hearing signal" (*i.e.*, determine the effects of FX-322 as a treatment for SNHL); (ii) "evaluate repeat dosing" to, among other things, determine how much FX-322 was needed to treat SNHL; (iii) and "clarify endpoints and patient population for registration" (*i.e.*, determine the types of patients that would benefit from treatment with FX-322). Phase 2a also had several "exploratory endpoints" to test the effect of treatment with FX-322 on: (i) "word recognition," (ii) "words-in-noise" (how well someone understands a word when there is background noise); (iii) pure ton audiometry; (iv) quality of life; and (v) "tinnitus."

5. The Company repeatedly represented that the trials were being done on an unbiased and appropriate sample population. For example, in the October 2020 investor presentation, it stated that Phase 2a was a "double-blind, placebo-controlled, multi-center" study of "adults ages 18-65" all of whom "***have meaningful word recognition deficits***." [Emphasis added.] Similarly, a January 2021 investor presentation stated that the Phase 2a "***entrance criteria required all subjects have meaningful word recognition deficits***." [Emphasis added.] And, as Frequency's

CDO, LeBel told investors on January 19, 2021, "***we have not disclosed what that deficit is to minimize any bias from the patients***." [Emphasis added.]

6. "Bias" in the context of developing a drug like FX-322 refers to systematic error in a study that could intentionally (or unintentionally) skew a study's results and undermine the validity of the study's findings. Bias can be the death knell for a clinical trial of a new drug because it undermines the validity of the results of the study as it becomes very difficult, if not impossible, to determine whether any effects of the treatment are actually caused by the drug or, instead, if those effects are just the result of bias. Moreover, certain biases are also likely to lead to anomalous and unrepresentative results, which is what happened here.

7. The bias that ultimately infected Phase 2a was what is termed "self-selection bias" or "volunteer bias" which occurs when individuals with certain characteristics intentionally and disproportionately enroll in a study. A self-selection bias results in a study with a patient population that is not truly representative of the intended patient population. Consequently, the results of the study are highly unlikely to be generalizable to the full population and much more likely to fail to show efficacy of the drug being tested. The danger of self-selection bias in Phase 2a was particularly acute because the study only enrolled 95 patients so the study's results could be biased by the presence of even a handful of patients.

8. Enrollment in Phase 2a was completed in September 2020. Each patient in Phase 2a was randomized into one of four treatment cohorts: (i) 24 patients received one dose of FX-322; (ii) 24 patients received two doses; (iii) 24 patients received four doses; and (iv) 24 received a four-dose placebo.[1] Patients received received weekly injections of FX-322 or the placebo in

[1] Strangely, the Company has repeatedly stated that Phase 2a enrolled 95 patients ***and*** that the four treatment cohorts each had 24 participates (for a total of 96 patients). Plaintiff has identified no explanation for this one-patient discrepancy.

one ear and were then tracked weekly for 210 days after the first injection. Frequency then first assessed Phase 2a's results 90 days after completion of the regimen and again in the months after.

9. According to the records publicly available from the FDA, Phase 2a was completed in December 2020, around 90 days after the completion of enrollment in Phase 2a. By this time, Defendants, however, ***already knew that Phase 2a was hopelessly biased*** (as the Company would confirm on March 23, 2021) and thus very unlikely to produce meaningful data to support the efficacy of FX-322 as a treatment for SNHL.

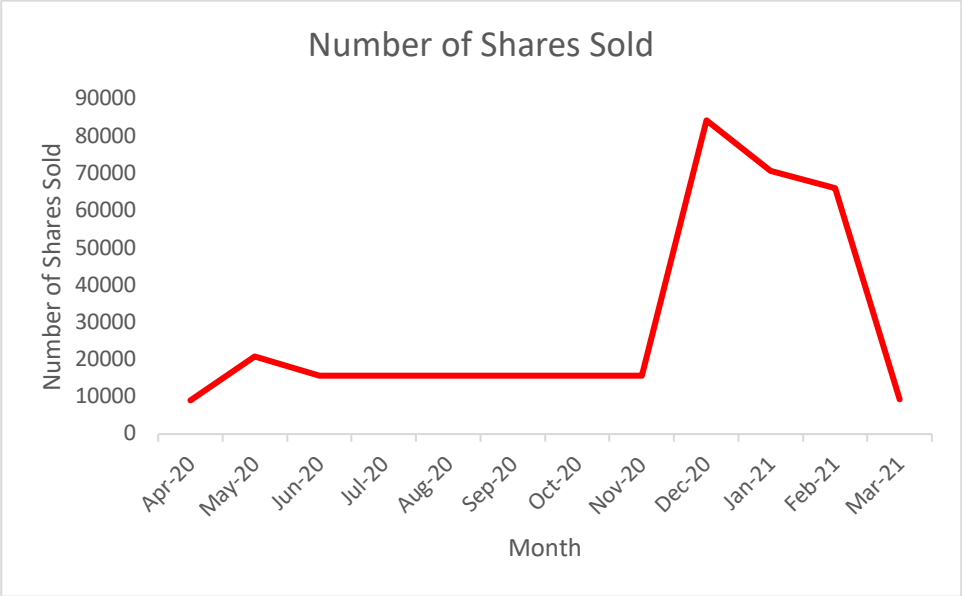
10. Plaintiff's investigation to date shows this hopeless bias and that, for example, individuals were able to enroll in Phase 2a by, in part, faking certain word recognition tests to make themselves appear more hearing impaired than they were and thus eligible to participate in Phase 2a when they otherwise would not have been enrolled in the study. As detailed further below, there are thousands of posts on tinnitus-specific internet message boards that discuss FX-322 as a potential cure for tinnitus (in addition to SNHL). Individuals on these message boards frequently discussed trying to enroll in Phase 2a to obtain early access to what they believed could perhaps be a cure for tinnitus. Importantly, Plaintiff has identified a post from February 2020 (while enrollment was ongoing) that details the specific word recognition score a patient would need to achieve to qualify for Phase 2a. This is precisely the information LeBel claimed in January 2021 was not "***disclosed . . . to minimize any bias from the patients.***" [Emphasis added.]

11. Information obtained from a confidential witness further confirms that Defendants knew that Phase 2a was tainted by self-selection bias. Plaintiff's confidential witness ("CW1") was the Senior Manager of Clinical Operations at Frequency from January 2018 until September 2021. As detailed below, CW1 worked with LeBel and others at the Company to develop the design of Phase 2a and was well situated to have inside information regarding Phase 2a and, in

particular, the sample population. After Phase 2a commenced, CW1 helped to oversee the implementation of Phase 2a on behalf of Frequency. CW1 confirmed that multiple patients enrolled in Phase 2a had qualified for and participated in the study despite not having met the inclusion criteria for the study. According to CW1, such individuals simply "faked being deaf" in order to enroll in Phase 2a. CW1 further revealed that duing the Class Period, Defendants were well aware the Phase 2a's inclusion and exclusion criteria, including criteria that were not supposed to be disclosed publicly, were being disseminated online via online posts (like those described immediately above and detailed further below).

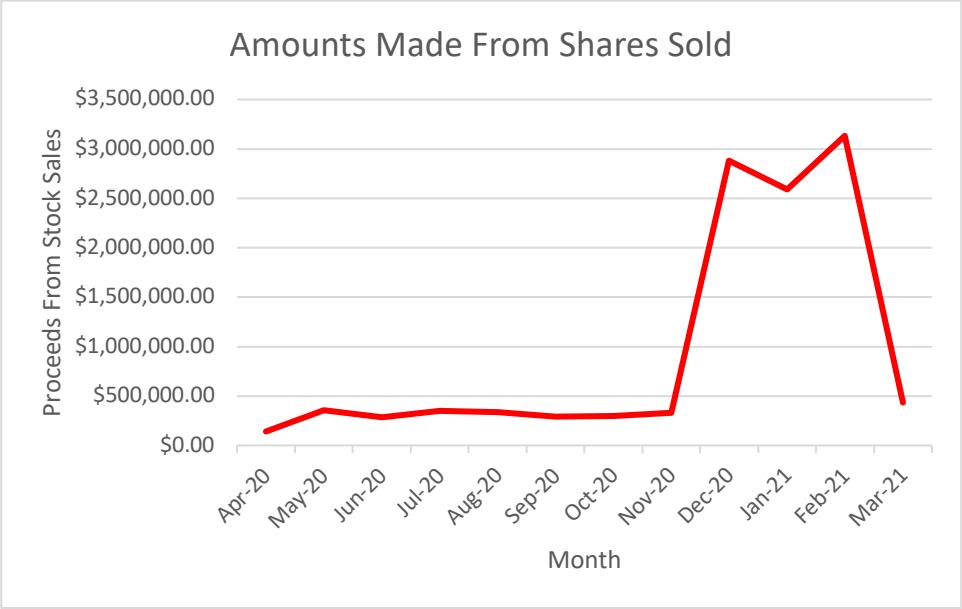
12. In addition, CW1 said that many of the Phase 2a "investigators" — *i.e.*, the doctors responsible for administering the drug (or placebo) directly to patients and tracking them after treatment — had identified a concerning discrepancy between certain patients' responses during the screening process for admission into Phase 2a and subsequent examinations by the investigators. Specifically, at screening these patients informed the investigators that they could not hear certain sounds at varying decibel levels but in subsequent examinations reported being able to hear those same sounds. According to CW1, several investigators contacted LeBel about this discrepancy to express their concerns to him.

13. Rather than disclose these known adverse facts about Phase 2a, Defendants continued to tell investors that patients in Phase 2a all had "***meaningful word recognition deficits***." [Emphasis added.] This enabled Lucchino to take advantage of Frequency's elevated stock price to earn millions in illicit insider trades. The chart below details the number of Frequency common shares Lucchino sold each month, starting with his first sale of stock on April 17, 2020 and ending with his final sale during the Class Period, in March 2021:



14. As shown above, the rate of Lucchino's sales increased during the Class Period and dramatically in December 2020 (the month when Phase 2a concluded). During the Class Period, Lucchino sold on average over 57,000 shares per month, which is dramatically out-of-line with his stock sales prior to the start of the Class Period, when he sold on average just over 15,000 shares per month.

15. In addition to accelerating the rate at which he dumped his shares after Phase 2a concluded in December 2020, Lucchino's Class Period sales were also significantly more profitable, as shown in the chart below. This chart shows how much money Lucchino earned each month selling Frequency shares, starting with his first sale of stock on April 17, 2020 and ending with his final sale during the Class Period, in March 2021. In total, Lucchino earned over $9 million from selling his inflated shares during the Class Period:



16. Unfortunately for investors, the revelation of Phase 2a's top-line results was a disaster. On March 23, 2021 (just after Lucchino finished his selling spree), the Company issued a press release stating the "interim results show that four weekly injections [of FX-322] in subjects with mild to moderately [SNHL] ***did not*** demonstrate improvements in hearing measures versus placebo." [Emphasis added.] Worse still, the Company disclosed that "***[t]he Phase 2a interim results also showed an unexpected apparent level of hearing benefit in the placebo group that did not occur in previous trials and exceeded well-established published standards, potentially suggesting bias due to trial design. Given these challenges observed in the Phase 2a study design, there was no discernible hearing benefit of FX-322 over placebo.***" [Emphasis added.]

17. Upon revelation of these results before the market opened on March 23, 2021, Frequency's shares fell from $36.29 to $7.99, ***a staggering 78% drop***, and a loss of approximately $955 million in the Company's market capitalization. Frequency's stock has never recovered and has been trading at less than $3 per share since March 2022.

JURISDICTION AND VENUE

18. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

19. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1331.

20. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). At all relevant times, Frequency was headquartered and conducted business in this District at 19 Presidential Way, 2nd Floor, Woburn, Massachusetts 01801. The Company is currently headquartered and conduts business in this District at 75 Hayden Avenue, Suite 300, Lexington, Massachusetts 02421. In addition, many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

21. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mail, interstate telephone communications, and facilities of national securities markets. All of the transactions in the securities that are at issue in this action took place within the United States.

PARTIES

A. Plaintiff

22. Lead Plaintiff Julian Quinones purchased Frequency shares at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures, as detailed in his Certification Pursuant to the Federal Securities Laws and accompanying papers (ECF Nos. 16-2, 16-3).

B. Defendants

23. Defendant Frequency is a pharmaceutical company based in Lexington, Massachusetts and incorporated in Delaware. Frequency's business is primarily focused on the development and commercialization of a hearing loss treatment called "FX-322." Frequency's stock trades on the Nasdaq Global Select Market ("Nasdaq") under the ticker "FREQ."

24. Defendant Lucchino is Frequency's CEO and President and is a director of the Company. CEO Lucchino is a co-founder of the Company and has earned millions from his role at Frequency. For example, CEO Lucchino's total compensation for fiscal year 2019 was over $7.3 million.

25. Defendant LeBel is Frequency's CDO and was responsible for overseeing the design and implementation of Phase 2a. LeBel is listed as the "Study Director" of Phase 2a in the FDA's records. LeBel joined frequency as in 2018 as the Company's CDO. Frequency has paid LeBel millions. For example, Lebel's total compensation in fiscal year 2019 was over $2.2 million. Defendants Lucchino and LeBel are referred to herein together as the "Individual Defendants."

26. Due to the Individual Defendants' positions at the Company, they possessed the power and authority to control the contents of Frequency's filings with the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be materially false, misleading, and incomplete prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company and their access to material non-public information available to them but not to the public, Individuals Defendants knew that the adverse

facts specified herein had not been disclosed to, but were being concealed from, the public, and that the statements at issue were materially false, misleading, and incomplete when made.

27. Frequency, LeBel, and Lucchino are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

I. FREQUENCY AND FX-322

28. Founded in 2014, Frequency went public in October 2019. The Company has never earned a profit in any fiscal year and is heavily dependent on the success of FX-322, which is the product the Company was founded to develop. Frequency is also developing a possible treatment for multiple sclerosis, but this product is still in thepreclinical stages of development.

29. FX-322 is a treatment Frequency is developing for patients with severe sensorineural hearing loss — or SNHL — which is believed to be caused in part by the depletion of hair cells inside the ear. FX-322 is a proprietary, small molecule drug that is intended to activate progenitor cells within the body. Progenitor cells are descendants of stem cells that then further differentiate to create special types of cells. In simple terms, the Company claims that an intratympanic injection of FX-322 directly into the ear can deliver FX-322 to the cochlea. Once in the cochlea, FX-322 purportedly activates progenitor cells within the body and triggers the regrowth of hairs in the ear.

30. A successful treatment for SNHL would be extremely lucrative. In its IPO offering documents, Frequency explained that it was motivated to develop FX-322 because the U.S. Food and Drug Administration ("FDA") had and has yet to approve any drug therapies for the treatment of SNHL.

31. Frequency performed several clinical trials of FX-322. The first trial was solely exploratory and tested whether FX-322 was therapeutically possible. The following "Phase 1"

and “Phase 1/2” studies tested the safety of FX-322. Phase 2a was designed to test whether FX-322 was effective as an actual treatment for SNHL.

32. The Phase 1/2 trial of FX-322, which was completed before Phase 2a started, enrolled only 23 patients with mild to moderately severe hearing loss to test solely the safety of FX-322. According to the Company’ October 2020 investor presentation, the results from the Phase 1/2 trial also showed that four of the six enrolled patients with moderate to moderately severe hearing loss had a “statistically significant and clinically meaningful improvement” in their hearing. The Company represented that this improvement in hearing was based upon measuring patients’ results on two tests: word recognition and words-in-noise.

33. In a word recognition test, a predetermined list of between 25 and 50 words is read out loud to the patient at a constant volume and the patient is asked to repeat the word he or she has just heard. A patient’s word recognition score is calculated by dividing the number of correctly repeated words by the total number of words on the list. For example, in a word recognition test with 25 words, a patient that correctly identifies 20 of the words will receive a word recognition score of 80%. As word recognition test and a resulting word-recognition score rely heavily on the patient accurately and truthfully reporting what he or she hears to the test’s administrator.

34. Similarly, a words-in-noise, or WIN, test consists of the administration of 70 monosyllabic words divided into two 35 word lists that are pre-recorded with a noisy background. A words-in-noise test is adaptive in that the loudness of the speech fluctuates during the test but the background noise remains constant. A words-in-noise score is calculated based upon how many monosyllabic words can be correctly identified by the patient. As with the word recognition test, the words-in-noise test and resulting words-in-noise score rely heavily on the patient accurately and truthfully reporting what she or he hears to the test’s administrator.

II. PHASE 2A

35. In light of the outcome of the Phase 1/2 study, in October 2019, the Company launched Phase 2a. As described in an October 2020 corporate slide deck, the "objectives" of Phase 2a were to: (i) "further establish hearing signal" (*i.e.*, determine the effects of FX-322 as a treatment for SNHL); (ii) "evaluate repeat dosing" to, among other things, determine how much FX-322 was needed to treat SNHL; and (iii) "clarify endpoints and patient population for registration" (*i.e.*, determine the types of patients that would benefit from treatment with FX-322). Phase 2a also had several "exploratory endpoints" to test the effect of treatment with FX-322 on: (i) "word recognition"; (ii) "words-in-noise"; (iii) pure ton audiometry; (iv) quality of life; and (v) "tinnitus."

36. Phase 2a was supposed to be a "double-blind, placebo-controlled, multi-center" study of "adults ages 18-65" all of whom "***have meaningful word recognition deficits***." [Emphasis added.] Phase 2a had a number of enrollment criteria that potential patients needed to meet in order to become part of the study, as well as certain exclusion criteria that would make a patient ineligible to participate in Phase 2a. Some of those criteria were published by the company, including on the FDA website. According to the FDA, those publicly-available criteria were as follows:

> Inclusion Criteria:
>
> 1. Adults aged 18-65 years inclusive.
> 2. Established diagnosis of stable sensorineural hearing loss by standard audiometric measures for ≥ 6 months prior to the Screening visit (no changes in air conduction greater than 10 dB at a single frequency or greater than 5 dB at two contiguous frequencies from the prior audiogram to the Screening audiogram in the study ear).
> 3. Documented medical history consistent with hearing loss being caused by noise exposure or sudden sensorineural hearing loss.

4. Pure Tone Audiometry (PTA) within 26-70 dB in the ear to be injected.

5. Female subjects must be of non-childbearing potential or will need to utilize two methods of highly effective contraception during the study participation (*e.g.* hormonal contraception or an intrauterine device and condoms) or remain abstinent. Male subjects should use condoms with spermicide during the course of the study or remain abstinent. Subjects should not donate sperm or ova during the study period.

Exclusion Criteria:

1. Previous participation in FX-322 clinical trial.

2. Currently on any medication consisting of valproic acid, valproate sodium, or divalproex sodium.

3. Perforation of tympanic membrane or other tympanic membrane disorders that would interfere with the delivery and safety assessment of an intratympanic medication or reasonably be suspected to affect tympanic membrane healing after injection in study ear. This includes a current tympanostomy tube.

4. Any conductive hearing loss of greater than 15 dB at a single frequency or greater than 10 dB at two or more contiguous octave frequencies in the study ear at the Screening visit or on the prior audiogram (if the Investigator feels there is not a true conductive hearing loss, the Medical Monitor should be consulted).

5. Active chronic middle ear disease or a history of major middle ear surgery, as an adult, in the ear to be injected.

6. Subject has had an intratympanic injection in either ear within 6 months of the screening visit.

7. History of clinically significant vestibular symptoms at the discretion of the investigator.

8. History of clinically significant systemic autoimmune disease.

9. History of head or neck radiation treatment or exposure.

10. History of platinum-based chemotherapy treatment.

11. Exposure to another investigational drug within 28 days prior to injection of study drug.

12. Evidence of any active or chronic disease or condition that could interfere with, or for which the treatment of might interfere with, the conduct of the

> study, or that would pose an unacceptable risk to the subject in the opinion of the investigator following a detailed medical history, physical examination, and vital signs (systolic and diastolic blood pressure, pulse rate, body temperature).
>
> 13. History of substance abuse within 2 years of the Screening Visit.
>
> 14. Positive test for drugs of abuse at screening.
>
> 15. Positive urine pregnancy test or breast-feeding.
>
> 16. Any known factor, condition or disease that, in the view of the Investigator, might interfere with treatment compliance, study conduct or interpretation of the results (*e.g.* previous high-dose aminoglycoside treatment).

37. In addition to the publicly disclosed inclusion and exclusion criteria listed above, Phase 2a also had "secret," purportedly undisclosed word-score inclusion criteria. Specifically, all patients needed to score below a certain threshold on a word recognition test. The threshold was established by Frequency as a part of the study design and allegedly to be withheld from the public so as not to bias the entire study.

38. Enrollment in Phase 2a was completed in September 2020. To enroll in Phase 2a, patients had to provide copies of their medical records and, specifically, audiograms, which are graphs plotting the results of a pure-tone hearing test showing how loud sounds need to be at different frequencies to be heard by the patient. All potential enrollees also had screening interviews during which they were asked a series of questions about their hearing loss and medical symptoms by a Phase 2a investigator. Importantly, patients also had to undergo a word recognition test as part of the in-person screening process (and possibly other tests as well).

39. Each patient in Phase 2a was then randomized into one of four treatment cohorts: (i) 24 patients received one dose of FX-322; (ii) 24 patients received two doses; (iii) 24 patients received four doses; and (iv) 24 received a four-dose placebo. Each patient received a weekly injection into one ear containing either FX-322 or placebo and were then tracked weekly for 210

days after the first injection. Frequency first assessed the Phase 2a's results 90 days after completion of the regimen and again in the months after.

40. Concurrently with the start of the Phase 2a study, in its 3Q 2019 Form 10-Q issued on November 18, 2019, Frequency announced that it would release the results obtained from the study "in the second half of 2020."

41. The Company pushed back the deadline to release the results to the spring of 2021, blaming the delay on the ongoing COVID-19 pandemic in its FY 2019 Form 10-K filed on March 26, 2020.

III. BIAS TAINTED PHASE 2A

A. Bias in General

42. At a basic level, bias in the context of a clinical trial refers to any systematic error in a study that encourages one outcome over others. Bias leads to a distortion of the true effects of the drug being studied and will likely result in a study that fails to show any statistically significant or otherwise meaningful results. There are many different biases in clinical trials. For example, "selection bias" is consciously or unconsciously assigning patients with same traits to the same treatment group (*e.g.*, selecting all the men in the study to receive the treatment and all women to receive the placebo). Similarly, "detection bias" occurs when study results are recorded, consciously or unconsciously, in a way that favors the desired outcome of the study.

43. Bias can be the death knell for a clinical trial of a new drug because it undermines the validity of the study's results. It becomes very difficult, if not impossible, to determine whether any effects of the treatment are actually caused by the drug or, instead, if those effects are just the

result of bias. Moreover, certain biases are also likely to lead to anomalous and unrepresentative results, which is what happened here.[2]

44. Given how severely biases can undermine an entire clinical trial, there are well-established ways to design a study to mitigate biases. For example, selection bias can be controlled by randomizing who receives the treatment and who receives the placebo, while detection bias can be controlled by "blinding" the investigator as to whether a patient has received the drug or the placebo.

45. This action concerns a systematic error in Phase 2a's caused by "self selection bias" or "volunteer bias": Patients were able to intentionally enroll in the study notwithstanding the fact that they did not meet all of Phase 2a's inclusion criteria. Clinical trials are intended to test drugs on a pre-specified group of patients that is representative of the entire population that has the condition that the drug is intended to treat (in this case, SNHL). Self-selection bias occurs when individuals with certain characteristics intentionally and disproportionately select themselves into a study. As a result of this bias, the pre-specified group of patients in the study ends up not being representative of the entire population. Consequently, the results of a clinical trial infected by self-selection bias cannot be generalized to the larger population and are much more likely to fail to show any meaningful or statistically significant effects.

46. As described in an article from the Journal of Otolaryngoloty — Head and Neck Surgery related to a hearing-loss study, "[r]ecruting an unbiased patient sample population is vital for the scientific rigor of medical research."[3] As such, "[s]elf-selection bias threatens internal

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[2] *See, e.g.*, Tobias Gerhard, "Bias: Considerations for Research Practice," AM. J. HEALTH-SYSTEM PHARM., Vol. 65, Iss. 22, 2159 (2008).

[3] Judith E. C. Lieu & Karuna Dewan, *Assessment of Self-Selection Bias in Pediatric Unilateral Hearing Loss Study*, 142 OTOLYRANGOLOGY — HEAD AND NECK SURGERY 427 (2010).

validity when study groups differ" and "[t]he external validity or generalizability of studies is compromised when differences between those who do and do not participate suggest that participates do not represent the target population."[4]

47. As detailed herein, Defendants knew (or recklessly disregarded) that patients in Phase 2a intentionally misidentified (or failed to identify) words spoken to them as part of a word recognition test, which caused those patients to have artificially low word-recognition scores and thus become eligible for Phase 2a. By self-selecting into Phase 2a in this way, these patients ultimately tainted the study's results by creating a sample that had better hearing than the overall population with SNHL.

B. Bias in Phase 2a

48. The evidence Plaintiff has uncovered so far suggests that at least some patients suffering from tinnitus faked their word recognition tests when they were screened for Phase 2a to obtain early treatment with FX-322. The way to obtain such early access was by participating in a study.

49. Tinnitus commonly presents as a ringing in one or both ears, but it can also sound like roaring, clicking, hissing, or buzzing. Tinnitus is not a disease but rather a symptom of an underlying issue with the auditory system, which can be caused by different health conditions, such as noise-induced hearing loss, ear and sinus infections, brain tumors, and thyroid abnormalities, among other things. There is currently no FDA-approved cure for tinnitus. In severe cases, tinnitus can cause people to have difficulty concentrating and sleeping, and it can interfere with a person's daily life and has even been linked to suicide. As a result, individuals with severe tinnitus are notoriously desperate for a cure.

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[4] *Id.*

50. The belief that FX-322 could possibly be a cure for tinnitus originated with patients that took part in the Phase 1 trials for FX-322 and anecdotally reported an improvement in their tinnitus after being treated with the drug. Those anecdotes were at least partially confirmed by LeBel. In July 2020, LeBel was interviewed on a podcast called "Tinnitus Talk" (which is related to the online tinnitus support group detailed below, *see* ¶¶51-57). Lebel was asked if there were "any anecdotes or patient testimonials that kind of corroborate" that FX-322 "might have a profound effect on tinnitus." He responded: "[W]e don't have data. Certainly there is anecdotal reports as patients have come back and visited with ENTs when they have had conversations with them about how they are doing. ***Some of them have offered that they have had improvements in tinnitus***, there's nothing that we can quantitate there. Again, ***it adds to the excitement of the opportunity***" of FX-322. [Emphasis added.] The fact that one of Phase 2a's exploratory end points was to test the impact of FX-322 on tinnitus was also frequently cited on tinnitus message boards as evidence that FX-322 could potentially treat tinnitus.

51. Plaintiff has identified numerous online message boards discussing FX-322 as a potential treatment for tinnitus. For example, the Tinnitus Talk forum, which is an online support group for sufferers of tinnitus,[5] has an entire message board related to FX-322, including Phase 2a (and the Company's prior clinical trials). According to one of the website's founders, as of July 2020, the FX-322 thread on the Tinnitus Talk forum had around 9,000 posts and nearly a million views. Currently, that thread is nearly 650 pages long, with much of the discussion — hundreds, if not thousands of posts — related to Phase 2a.

[5] *See* https://www.tinnitustalk.com/.

52. Whether and how to enroll in Phase 2a was a frequent topic of discussion on the Tinnitus Talk forum with many individuals motivated by a desire to gain early access to FX-322 and a potential cure for their tinnitus. As one forum member put it in a post from December 2019:

> I can tell you that if I could get my hands on FX-322 I'd get shot into my ear today. I have no material concerns that it would harm me given where it is in the approval process. People are literally killing themselves over tinnitus – the risks are worth the potential reward.[6]

Similarly, a different forum member remarked in October 2019, "If you really want this [(*i.e.*, FX-322)], participate in a trial."

53. Several individuals on the Tinnitus Talk forum reported that they had tried to enroll in Phase 2a and had been rejected. The reasons for those rejections were likewise a heavily discussed topic, which often focused around Phase 2a's enrollment inclusion and exclusion criteria. The publicly available inclusion and exclusion criteria were often quoted and discussed at length of the forum. For example, in a post from November 2019, one forum member said "here is the exclusion criteria" and then listed the 16 publicly available study criteria as they appeared on the FDA's website (*see supra* ¶36).

54. Forum members also compared hearing test results to determine if they were eligible to enroll in Phase 2a. For example, in November 2019 one forum member asked another forum member, "Can you share your audiogram with me if you don't mind? I still need to get an updated one because mine's like a year old but I feel like my hearing is not bad enough for me to qualify" for Phase 2a.

[6] Post on the Tinnitus Talk forums are made under pseudonyms. In an effort to protect the privacy of the individual's whose posts are quoted in this Complaint, Plaintiff has omitted or, as necessary, further anonymized the usernames of members of the Tinnitus Talk forums.

55. Most importantly, Phase 2a' purportedly undisclosed word recognition inclusion criteria were openly discussed on the Tinnitus Talk forum.[7] On February 13, 2020 — while Phase 2a was still actively enrolling patients and a full seven months before enrollment ended — Form Member A made the following post on the FX-322 forum:

> So quick update everyone:
>
> Unfortunately[,] I was officially rejected. ***The reason they gave is that they need at least 85% or less word score recognition and mine is 100%*** (which is slightly odd because I did say several times I couldn't understand the words but shrug).
>
> ***I know a lot of people asked for the reason they were rejected and weren't give one but the Torrance location seems to be extremely forthcoming with information, and didn't hesitate to tell me at all.*** Not sure why.
>
> But ultimately it looks like they are looking for a combination of audiogram loss and depleted word scores. Best of luck to anyone still trying to get in.
>
> [Emphasis added.]

56. In fact, on March 23, 2021 — the very day the Company revealed the bias in Phase 2a — that same Forum Member A posted the following on the FX-322 forum:

> ***I actually fear I might have been unknowingly complicit in the whole fraud thing, if that turns out to be truly legitimate. Most people were not given the reason for their rejection from the Phase 2a trial, but I was.***
>
> ***They point blank told me that although my audiogram qualified me, my WR scores did not, and I shared that here on the forums…*** my intention was to save people the hassle, money, and mental stamina of getting a HF audiogram if they (like me) had no WR issues. Because it ultimately wouldn't matter even if you had measurable notches.
>
> ***But now I see why most testing sites would not disclose the reason why people were rejected . . . because if you knew that the WR scores were the lynch pin you could more easily lie your way into the trial.***
>
> God I feel like I really fucked up.
>
> [Emphasis added & ellipses in original.]

[7] Plaintiff has reason to believe that the word recognition criteria may also have been disclosed on other online forums — a fact which can be established through the discovery process.

57. In response to Forum Member A's March 23 post, a different forum member responded with the following: "I'm wondering whether what you're saying does hold some truth, not essentially in respect of you but more generally. ***Didn't Lucchino say something along the lines that they learned from social media points of enquiry that patients had been sharing the WR entry criteria?***"[8] [Emphasis added.]

C. CW1 Confirms Bias in Phase 2a and Defendants' Knowledge Thereof

58. The evidence Plaintiff has uncovered from the Tinnitus Talk forum is consistent with what Plaintiff learned from CW1.

59. CW1 worked at the Company from January 2018 until September 2021 as the Senior Manager of Clinical Operations. CW1 initially reported to Frequency's Director of Clinical Operations until February 2018, at which point she reported to the Company's then CDO, Raj Manchanda, until Mr. Manchanda left frequency in September 2018. At this point, CW1 began reporting directly to LeBel, until sometime after February 2021 when the Company promoted a new Director of Clinical Operations.

60. As the Senior Manager of Clinical Operations, CW1 was involved in all of the clinical operations of the Company at all relevant times, including the design, development, and administration of clinical trials. CW1 was the Trial Manager for Phase 2a and worked hand-in-hand with LeBel to design Phase 2a, including preparing dozens of drafts of the study's protocols to respond to comments from the FDA. According to CW1, Phase 2a was conducted at a variety of locations throughout the U.S., all of which were medical practices of ear, nose, and throat specialists who regularly treated hearing loss. The doctors at these practices enrolled patients from their existing patient pools, among others, and then administered the FX-322 injections on site.

[8] Plaintiff believes that this reference to a statement from Lucchino refers to a comment made on a March 23, 2021, investor call for which there is no publicly available transcript or recording (*see infra* ¶81).

CW1 personally visited sites around the country where the study was being administered to make sure Phase 2a was being conducted properly and that the data were being captured and reported accurately. During Phase 2a, CW1 had access to the study's data while the trial was going on.

61. CW1 explained that a significant challenge in designing clinical studies is to do so without unintentionally divulging information that could result in bias. Specifically, CW1 stated that in designing Phase 2a the Company — CW1, LeBel and others — attempted to mitigate the potential bias that could arise from enrolling patients who did not actually meet the study's enrollment criteria. CW1 said it was common for individuals to try and fake their way into a clinical trial by misrepresenting the nature of scope of their medical issues. CW1 further stated the LeBel was aware of this pervasive practice.

62. CW1 reported that, despite these alleged efforts, participation in Phase 2a was discussed on the Tinnitus Talk forum. According to CW1, even the inclusion and exclusion criteria for the study (as corroborated by Plaintiff's investigation) appeared on the forum. This information enabled would-be trial participants that did not qualify for Phase 2a to become enrolled in the study by providing false answers during the screening process.

63. CW1 also made it clear that the Company learned about the potential issues with Phase 2a, in part, from online posts that contained the study's inclusion and exclusion criteria. Indeed, Frequency personnel identified posts where persons discussed Phase 2a in detail and that some of these posts expressly contained the very inclusion and exclusion criteria for the study because they contained uploaded copies of trial-related materials. Due to CW1's position at the Company and role in Phase 2a, CW1 was in a position to know this information.

64. Given the importance of Phase 2a to the Company and the potentially devastating impacts bias could have on that study, the most reasonable inference from CW1's account is that

the online posts identified by Company personnel and the significance of those posts to the prospects of Phase 2a must have been known to Lucchino and LeBel. Furthermore, LeBel was certainly aware of "Tinnitus Talk," having appeared on the podcast in July 2020.

65. CW1 also detailed how the Company was aware of the self-selection and volunteer bias from the reports of "investigators"—*i.e.*, the doctors responsible for administering the drug (or placebo) directly to patients and tracking them after treatment. CW1 said that many of the Phase 2a investigators had identified a concerning discrepancy between certain patient's responses during the screening process for admission and subsequent examinations by the investigators. Specifically, at screening, these patients informed the investigators that they could not hear certain sounds at varying decibel levels. Then, in subsequent examinations, they reported being able to hear those same sounds. According to CW1, ***several investigators contacted LeBel about this discrepancy to express their concerns to him***. Again, CW1 worked directly with the investigators, even claiming to have a "very good relationship with all the physicians," so was in a position to know this information.

IV. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

66. Throughout the Class Period, Defendants painted a rosy picture of Phase 2a despite knowing that the study was hopelessly biased and thus unlikely to deliver results that could support the efficacy of FX-322 as a treatment for SNHL.

67. The Class Period begins on October 29, 2020, when the Company issued a press release entitled "Frequency Therapeutics Announces Expanded FX-322 Clinical Development and Upcoming Day-90 Phase 2a Analysis" and posted a corporate slide presentation to the Company's website. Both that press release, and the slide deck were filed with the SEC on October 29, 2020 on Form 8-K. The October 29, 2020 press release stated that that "[t]he Phase 2a study completed enrollment with 95 patients in September 2020" and that patients in Phase 2a had "mild to

moderately severe acquired SNHL." The press release quotes the following statement from LeBel, "we expect that [Phase 2a] data will enable us to refine the design and endpoints of future studies ***and provide a fuller understanding of the effects of FX-322 on hearing clarity***." [Emphasis added.]

68. The October 29 corporate slide presentation unequivocally represented that in Phase 2a "***all subjects have meaningful word recognition deficits***" and that "study enrollment completed Sept. 2020." [Emphasis added.]

69. The statements set out in ¶¶67-68 were materially false, misleading, incomplete, and inaccurate — both individually and in combination — because they conveyed that (i) the Company "completed enrollment of 95 patients in Phase 2a" that met the inclusion criteria of "mild to moderately severe acquired SNHL"; (ii) data from Phase 2a could actually "provide a fuller understanding of the effects of FX-322 on hearing clarity"; and (iii) in Phase 2a "all subjects have meaningful word recognition deficits." In reality, as Defendants knew or recklessly disregarded, Phase 2a enrolled patients that did not actually meet the study's inclusion criteria. In fact, as Defendants well knew and failed to disclose, enrolled individuals had faked their word recognition screening tests and had hopelessly biased Phase 2a to the point where it was very unlikely the study would produce statistically significant results in favor of FX-322. Moreover, Defendants had a duty to disclose this known bias in Phase 2a (i) in order to make their statements about the Phase 2a study not materially misleading, and (ii) because Defendants chose to speak about Phase 2a's patient enrollment and thus had to speak the complete truth on that topic.

70. Then, on November 16, 2020, the Company released its third-quarter 2020 financial results, which were also filed on Form 10-Q with the SEC (the "3Q 10-Q"). In that release, Frequency stated that "[i]n September 2020, we completed enrollment of 95 patients in the Phase

2a clinical trial." In the press release accompanying the 3Q 10-Q, the Company stated that it was "expanding its FX-322 development program to evaluate FX-322's clinical profile in other SNHL patient types . . . in order to identify the broadest population that may benefit from the product candidate" and that "[t]he results of the Phase 2a end of study analysis . . . ***are expected to provide the basis for an end of Phase 2 meeting with the US Food and Drug Administration regarding potential pivotal studies of FX-322***," both critical milestones in new drug development. [Emphasis added.]

71. In that same press release, the Company further stated that "[t]he key efficacy objectives of the study are to evaluate the potential of FX-322 to improve hearing clarity or intelligibility as measured by improvements in tests of word recognition (WR) or words-in-noise (WIN)."

72. In that same press release, Defendant Lucchino added:

> ***This past quarter we continued to gain momentum***, completing study enrollment and moving toward a day-90 readout of the Phase 2a study of FX-322, while expanding our development program by adding additional studies to further our understanding of the potential of FX-322 to help the broadest SNHL patient population. ***The analysis of day-90 data will enable us to evaluate our key goals for the Phase 2a study and provide a comparison to the hearing improvement signal we observed in our Phase 1/2 study***.
>
> [Emphasis added.]

73. The statements set out in ¶¶70-72 were materially false, misleading, incomplete, and inaccurate — both individually and in combination — because they conveyed that (i) the Company "completed enrollment of 95 patients in Phase 2a" that met the inclusion criteria for that study; (ii) "[t]he results of the Phase 2a end of study analysis" could "provide the basis for . . . meeting with the US Food and Drug Administration regarding potential pivotal studies of FX-322"; and (iii) Phase 2a with the patients enrolled through September 2020 could actually "evaluate the potential of FX-322 to improve hearing clarity or intelligibility." In reality, as

Defendants knew or recklessly disregarded, Phased 2a enrolled that did not actually meet the study's inclusion criteria. In fact, as Defendants well knew and failed to disclose, enrolled individuals had faked their word recognition screening tests and had hopelessly biased Phase 2a to the point where it was very unlikely the study would produce statistically significant results in favor of FX-322. Moreover, Defendants had a duty to disclose this known bias in Phase 2a (i) in order to make their statements about the Phase 2a study not materially misleading, and (ii) because Defendants chose to speak about Phase 2a's patient enrollment and thus had to speak the complete truth on that topic.

74. The 3Q 10-Q also contained a purported "risk disclosure" related to the ***risks*** that ***could*** arise from a biased clinical trial. Specifically, the 3Q 10-Q stated:

> ***Clinical trial failure may result from*** a multitude of factors, including but not limited to, flaws in study design, dose selection, placebo effect, ***patient enrollment criteria, selection of patients based on patient misrepresentations***, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing.
>
> [Emphasis added.]

75. The statement set out in ¶74 was materially false, misleading, incomplete, and inaccurate because it only purported to warn of a future risk that "Clinical trial failure ***may*** result from . . . ***patient enrollment criterial [and] selection of patients based on patient misrepresentations***," when, in fact, as Defendants knew or recklessly disregarded, Phase 2a enrolled patients that did not actually meet the study's inclusion criteria, and that the bias had already occurred. [Emphasis added.] In fact, as Defendants well knew and failed to disclose, enrolled individuals had faked their word recognition screening tests and had hopelessly biased Phase 2a to the point where it was very unlikely the study would produce statistically significant results in favor of FX-322. Moreover, Defendants had a duty to disclose this known bias in Phase 2a (i) in order to make their statements about the Phase 2a study not materially misleading, and

(ii) because Defendants chose to speak about Phase 2a's patient enrollment and thus had to speak the complete truth on that topic.

76. Defendants continued to tout Phase 2a and, in particular, the testing population. On January 11, 2021, after the study ended, Frequency posted an updated corporate slide presentation in the "Investors & Media" portion of the Company's website, which was also filed with the SEC that day on Form 8-K. That slide presentation stated unequivocally that in Phase 2a "***[a]ll subjects have meaningful word recognition deficits***" and that Phase 2a's "***[e]ntrance criteria required all subjects have meaningful word recognition deficits.***" [Emphasis added.]

77. The statements set out in ¶76 were materially false, misleading, incomplete, and inaccurate — both individually and in combination — because they conveyed that (i) all subjects enrolled in Phase 2a actually had "meaningful word recognition deficits"; and (ii) that Phase 2a "required all subjects to have meaningful word recognition deficits." In reality, as Defendants knew or recklessly disregarded, Phase 2a enrolled patients that did not actually meet the study's inclusion criteria. In fact, as Defendants well knew and failed to disclose, enrolled individuals had faked their word recognition screening tests and had hopelessly biased Phase 2a to the point where it was very unlikely the study would produce statistically significant results in favor of FX-322. Moreover, Defendants had a duty to disclose this known bias in Phase 2a (i) in order to make their statements about the Phase 2a study not materially misleading, and (ii) because Defendants chose to speak about Phase 2a's patient enrollment and thus had to speak the complete truth on that topic.

78. Similarly, in a January 19, 2021, investor presentation attended by Lucchino and others, Defendant LeBel, Frequency's CDO, said the following about Phase 2a's design and enrollment:

> [I]n the phase 1 safety study, there was not requirement for anybody to fall within a range of word recognition. In fact, many subjects had almost perfect scores. So

> you can't see a signal due to ceiling effects in subjects that have a perfect score of 48 out of 50 words correct or so.
>
> In the phase 2A study, we've modified that. ***Every subject has to have a deficit. Now we have not disclosed what that deficit is to minimize any bias from the patients but everybody has to fall within a certain range in order to qualify for the study***.
>
> [Emphasis added.]

79. The statements set out in ¶78 were materially false, misleading, incomplete, and inaccurate because they conveyed that (i) "[e]very subject [in Phase 2a] has to have a deficit" in word recognition "within a certain range in order to qualify for the study"; and (ii) that the amount of that deficit was "not disclosed." In reality, as Defendants knew or recklessly disregarded, Phase 2a enrolled patients that did not actually meet the study's inclusion criteria. In fact, as Defendants well knew and failed to disclose, enrolled individuals had faked their word recognition screening tests and had hopelessly biased Phase 2a to the point where it was very unlikely the study would produce statistically significant results in favor of FX-322. Further, as Defendants knew or recklessly disregarded, that "the amount of [the] deficit" in word recognition necessary to qualify for enrollment in Phase 2a had long been disclosed publicly (as early as February 13, 2020) on the Tinnitus Talk forums and potential enrollees in the study were actively discussing ways to fake their way in to Phase 2a. Moreover, Defendants had a duty to disclose this known participant bias in Phase 2a (i) in order to make their statements about Phase 2a and study's word recognition deficiency enrollment criteria not materially misleading, and (ii) because Defendants chose to speak about Phase 2a's patient enrollment and thus had to speak the complete truth on that topic.

V. THE TRUTH EMERGES

80. Before the market opened on Tuesday, March 23, 2021, Frequency issued a press release entitled "Frequency Therapeutics Releases New Data from Two FX-322 Clinical Studies;

Plans to Advance Single-Dose Regimen," which was subsequently filed with the SEC on Form 8-K. The press release stated:

> Frequency Therapeutics, Inc. (Nasdaq: FREQ), today announced topline, day-90 data from its FX-322 Phase 2a study . . . . The interim results show that four weekly injections in subjects with mild to moderately sever [SNHL] ***did not demonstrate improvements in hearing measures versus placebo***."
>
> . . .
>
> While [word recognition]scores increased across all groups, repeated weekly injections appeared to dampen the hearing benefit observed compared to other single-injection studies. ***The Phase 2a interim results also showed an unexpected apparent level of hearing benefit in the placebo group that did not occur in previous trials and exceeded well-established published standards, potentially suggesting bias due to trial design. Given these challenges observed in the Phase 2a study design, there was no discernible benefit of FX-322 over placebo.***
>
> [Emphasis added.]

81. According to the March 23, 2021 press release, the Company held a conference call with investors at 8:30 a.m. Eastern that day to discuss the Phase 2a topline results. A transcript from that call was never filed with the SEC and Plaintiff has not identified any transcript or recording of that call from public sources, despite diligent efforts. A link on the Company's website to an apparent recording of the March 23 call also does not work. Thus, what else Defendants said to investors on March 23, 2021 about Phase 2a can only be obtained through discovery (although there are second-hand accounts of the call, like the one described in ¶85 below).

82. According to CW1, the fact that a high number of trial participants who had received the placebo ended up achieving much higher word recognition scores than anticipated strongly suggested that those patients did not actually have the level of hearing loss they had represented when being screened for the study. Rather, they had better hearing than what was

required to participate in Phase 2a and as such should not have been enrolled in the trial in the first place.

83. CW1 also explained that the self-selection bias was so severe and so detrimental to the study that, in subsequent studies (including the 2021 Phase 2b trial), the Company required investigators to sign confidentiality agreements before being told the hearing loss criteria. According to a January 2022 investor presentation, the Company also changed the Phase 2b screening process to require "multiple baseline measures" of the patients' hearing and "multiple speech perception tests" (like the word recognition test) in order to "[r]educe potential for bias" in Phase 2b.

84. Investors' reaction to the Company's corrective disclosures on March 23, 2021 was swift and punishing. That day, the value of Frequency's common stock plummeted from $36.29 at the close of trading on March 22, 2021 down to $7.99 at the close on March 23, 2021, ***a 78% drop. This precipitous decline erased approximately $955 million from the Company's market capitalization.***

85. Stock analyst reports and news articles directly attributed the March 23, 2021 decline in the Company's stock price to Frequency's revelation that Phase 2a had failed because the study was "biased." For example, on March 23, Bloomberg published an article on its website entitled "Frequency Slumps as Hearing Loss Treatment Study Disappoints." That article reported that "Frequency Therapeutics shares dropped the most intraday ever after the biotechnology company released disappointing results from a Phase 2a study of FX-322 for hearing loss treatment." The article went on to note that "***apparent level of hearing benefit in the placebo group [that] did not occur in previous trials . . . . potentially suggests bias due to trial design***."

[Emphasis added.] Similarly, an article written after the dust settled by stock analyst Andy Jones for the website Seeking Alpha reported the following:

> On its call related to [the Phase 2a] results, management said they think that four weekly injections temporarily overwhelmed the ear and produced an unfavorable biological response. This could potentially account for lower-than-expected word recognition scores in the treatment groups, ***but it doesn't explain why those groups failed to differentiate themselves from the efficacy seen in the placebo group . . . .***
>
> As far as why the FX-322 groups looked basically the same as placebo, management also said that the placebo response was oddly high in comparison to both the prior Phase 1/2 trial and historical data. ***Frequency believes that its inclusion criteria encouraged the enrollment of people with artificially low word recognition scores at baseline. Patients were apparently informed that they could only participate in the study if they had a word recognition deficit at baseline, so management makes it sound like patients may have been faking worse hearing than they actually had to make sure they could enroll.*** The company is now talking about having a non-interventional lead-in period with future trials. Patients' hearing would be measured at multiple points, so it would be far more difficult to consistently fake an artificially lower baseline hearing score.[9]
>
> [Emphasis added.]

86. In addition, in June 2022, the Company itself further confirmed that self-selection bias torpedoed Phase 2a. Specifically, on June 30, 2021, the Company released the final results from Phase 2a as part of an investor presentation that was filed with the SEC on Form 8-K. As with the top-line data from Phase 2a, the final results "showed that four weekly injections of FX-322 did not demonstrate improvements in any hearing measures versus placebo." The Company also confirmed "***there was an unexpected increase in WR scores in the placebo group that did not occur in previous FX-322 trials and exceeded well-established published standard***." [Emphasis added.] Frequency then admitted that "***given the lack of reliability of baseline WR scores of the placebo group due to potential bias in the trial design, the Company was unable to***

[9] Mr. Jones' article was published on April 20, 2021.

evaluate hearing improvements in WR scores for dosing regimens versus placebo." [Emphasis added.] The Company then stated the following regarding bias in Phase 2a:

> The Company observed unexpected, large changes from baseline in WR scores in the Phase 2a study placebo group that did not occur in previous FX-322 trials and exceeded well-established published standards. The Company believes these changes potentially suggest that the Phase 2a trial design resulted in bias that impacted baseline hearing measures and thereby limited the ability to evaluate hearing improvement versus placebo.
> . . .
> ***In addition, a review by the Company of available historical data from audiograms taken before the study, showed many study subjects with considerably lower baseline WR scores versus historical scores.*** This effect was observed among patients in all study groups. ***However, it was observed to be more frequent in the placebo group, and the level of WR scores at day-90 returned to values more consistent with historical data.*** Historical tests may also have been conducted with alternate word lists, lengths, or presentation levels.
>
> Increases in WR scores that exceeded the 95% CI for test/retest variability were also observed in some untreated ears. Patients were not aware which ear would be treated when they came in for their baseline visit, which suggests potential bias in the trial design. ***Another observation of potential bias was also seen in inconsistent efforts by subjects in completing WR tests. Specifically, subjects could forego responding to test words in order to have a WR deficit at baseline. For example, one placebo subject, had 22 "no responses" on a 50 WR test given to the patient at baseline, while only 3 "no responses" were provided at the day-90 WR test.***
>
> [Emphasis added.]

87. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities caused by thereby, Plaintiff and the other Class members have suffered significant losses and damages.

VI. ADDITION SCIENTER ALLEGATIONS

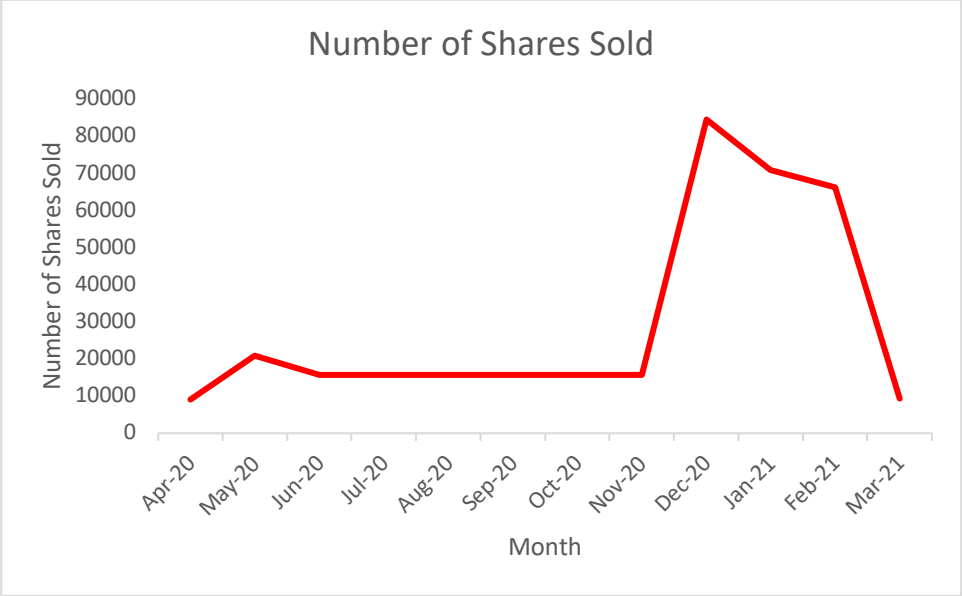
88. As alleged herein, Defendants acted with scienter in that they: (i) knew that the public documents and statements issued or disseminated in the name of the Company were materially false, misleading, and incomplete when made; (ii) knew that such statements or documents would be issued or disseminated to the investing public; and (iii) knowingly and

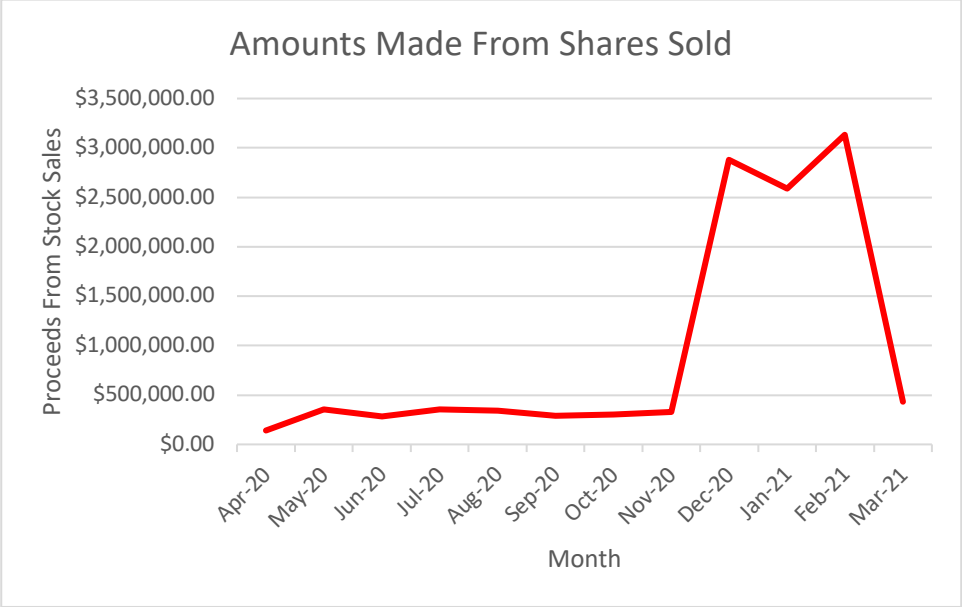
substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. The Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Phase 2a, their control over, and/or receipt and/or modification of Frequency's allegedly materially false, misleading, and incomplete statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Frequency, participated in the fraudulent scheme alleged herein.

89. Specifically, by at least October 29, 2020, Defendants knew (or recklessly disregarded) that Phase 2a was hopelessly biased because the study had enrolled a certain number of patients who had intentionally "faked" their test results to gain entry into Phase 2a. The exact date when Defendants learned of the bias in Phase 2a is something that can only be uncovered through discovery. CW1, however, stated that the Company learned about the self-selection bias in Phase 2a through online message board posts where potential study enrollees disclosed the study's inclusion and exclusion criteria, including the Phase 2a word recognition criteria that, according to LeBel, was supposedly "***not disclosed . . . to minimize any bias***." [Emphasis added.] As alleged above (¶55), Plaintiff's independent investigation has identified a post from as early as February 13, 2020, which discloses how much of a word recognition score (85% or less) needed enroll in Phase 2a.

90. Moreover, scienter can be inferred from the dramatic increase in CEO Lucchino's stock sales starting during the Class Period, just two months after enrollment in Phase 2a ended. The two charts below show the monthly volume of CEO Lucchino's sales and the amount of money he made from those sales starting with his first ever public sale of Frequency stock in April 2020 and ending in March 2021. As is evident from these charts, CEO Lucchino's sales were

clearly timed to take advantage of Frequency's elevated stock price before results from Phase 2a were revealed to investors.





91. As shown above, the rate of Lucchino's sales increased during the Class Period and dramatically in December 2020 (the month when Phase 2a concluded). During the Class Period, Lucchino sold on average over 57,000 shares per month, which is dramatically out-of-line with his stock sales prior to the start of the Class Period, when he sold on average just over 15,000 shares

per month. In addition to accelerating the rate at which he dumped his shares after Phase 2a concluded in December 2020, Lucchino's Class Period sales were also significantly more profitable, as shown above. In total, Lucchino earned over $9 million selling his shares at inflate prices during the Class Period.

92. Finally, scienter can be inferred by the importance of Phase 2a to the "core operations" of Frequency. For example, as the Company stated in its November 16, 2020 press release, FX-322 was Frequency's "lead product candidate for the treatment of acquired SNHL" and its only other potential product — a treatment for multiple sclerosis — is still in early, preclinical development. As Lucchino is quoted as saying in that same press release, Phase 2a "will enable us to evaluate our key goals . . . and provide a comparison to the hearing improvement signal we observed" in prior studies. Lucchino is also quoted in that press release as saying the Phase 2a "data are also expected to provide critical insights as we look ahead to the end-of-study readout . . . and enable us to plan our longer-term development and regulatory strategies." Similarly, the 3Q 10-Q stated that Frequency is "heavily dependent on the success of FX-322 . . . and if FX-322 does not receive regulatory approval or is not successfully commercialized, our business will be materially adversely harmed." In other words, at the time, Phase 2a was critical to the future development of FX-322 and, thus, the Company's commercial prospects. As such, there can be no doubt that Defendants knew of (or, at best, recklessly disregarded) that Phase 2a had been compromised by the enrollment of patients that did not meet the study's inclusion criteria. Importantly, knowing that Phase 2a was biased in this way did not require Defendants to know the results of the study. Instead, the results from Phase 2a would merely confirm (and did confirm) the degree to which bias undermined Phase 2a's results.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

93. Plaintiff brings this action as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all those who purchased or otherwise acquired Frequency's common stock during the Class Period and were damaged upon the revelation of the alleged corrective disclosure (the "Class"). Excluded from the Class are the Defendants named herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

94. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Frequency's common stock was actively traded on the Nasdaq in the United States. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Frequency or its transfer agent and/or the Nasdaq and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

95. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

96. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

97. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations, and management of Frequency;

(c) whether Defendants Lucchino and LeBel caused Frequency to issue false and misleading statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(e) whether the prices of Frequency's common stock during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

98. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable.

99. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

PRESUMPTION OF RELIANCE

100. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) Frequency's common stock is traded in an efficient market;

(d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company's securities were traded on the Nasdaq in the United States;

(f) the Company was covered by securities analysts;

(g) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(h) Plaintiff and members of the Class purchased, acquired, and/or sold Frequency's common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed without knowledge of the omitted or misrepresented facts.

101. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

102. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violations of §10(b) of the Exchange Act and Rule 10b-5 (Against All Defendants)

103. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

104. This Count is asserted against Defendants and is based upon §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

105. During the Class Period, Defendants engaged in a plan, scheme, conspiracy, and course of conduct pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes, and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Frequency's common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Frequency's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

106. Pursuant to the above plan, scheme, conspiracy, and course of conduct, Defendants participated directly or indirectly in the preparation and/or issuance of the annual reports, SEC filings, press releases, and other statements and documents, as described above, including statements made to securities analysts and the media, that were designed to influence the market for Frequency's common stock. Such reports, filings, releases, and statements were materially

false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Frequency's business and operations.

107. By virtue of their positions at Frequency, Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Individual Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted, as described above.

108. Further information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As a senior manager and/or director of Frequency, the Individual Defendants had knowledge of the details of Frequency's internal affairs.

109. Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, Defendants Lucchino and LeBel were able to, and did, directly or indirectly, control the content of the statements of Frequency. As officers and/or directors of a publicly held company, Defendants Lucchino and LeBel had a duty to disseminate timely, accurate, truthful, and complete information with respect to Frequency's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Frequency's common stock was artificially inflated throughout the

Class Period. In ignorance of the adverse facts concerning Frequency's business and financial condition, which were concealed by Defendants, Plaintiff and other members of the Class purchased or otherwise acquired Frequency's common stock at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or statements disseminated by Defendants, and were damaged thereby.

110. During the Class Period, Frequency's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired Frequency's common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired shares at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Frequency's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Frequency's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

111. By reason of the conduct alleged herein, Defendants have knowingly or recklessly, directly or indirectly, violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

112. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure

that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Violations of §20(a) of the Exchange Act (Against the Individual Defendants)

113. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

114. During the Class Period, the Individual Defendants participated in the operation and management of Frequency and conducted and participated, directly and indirectly, in the conduct of Frequency's business affairs. Because of his senior positions as the Company's CEO and President, Defendant Lucchino knew of the adverse non-public information alleged herein. Similarly, because of his senior position as the Company's CDO and his oversight of Phase 2a, Defendant LeBel knew of the adverse non-public information alleged herein.

115. As an officer and/or director of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, with respect to Frequency's business practices, and promptly correct any public statements issued by Frequency that had become materially false or misleading.

116. Because of their positions of control and authority as a senior director and/or officer and/or executive team members, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings that Frequency disseminated in the marketplace during the Class Period concerning the Company's business, operations, and Phase 2a. Throughout the Class Period, Individual Defendants exercised their power and authority to cause Frequency to engage in the wrongful acts complained of herein. Individual Defendants, therefore, were each a "controlling person" of Frequency within the meaning of §20(a) of the

Exchange Act. In this capacity, Individual Defendants participated in the unlawful conduct alleged herein that artificially inflated the market price of Frequency's common stock.

117. Individual Defendants, therefore, each acted as a controlling person of Frequency. By reason of their senior management positions and/or being a director of Frequency, Individual Defendants had the power to direct the actions of, and exercised the same, to cause Frequency to engage in the unlawful acts and conduct complained of herein. Individual Defendants exercised control over the general operations of Frequency and possessed the power to control the specific activities that comprise the primary violations about which Plaintiff and the other members of the Class complain.

118. By reason of the above conduct, Individual Defendants are liable pursuant to §20(a) of the Exchange Act for the violations committed by Frequency.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and relief as follows:

A. Determining that the instant action may be maintained as a class action under Fed. R. Civ. P. 23 and certifying Plaintiff as Class Representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: May 16, 2022

SCOTT+SCOTT ATTORNEYS AT LAW LLP

s/ Amanda Lawrence

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Attorneys for Lead Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

s/ Amanda F. Lawrence
Amanda F. Lawrence (BBO# 568737)